EXHIBIT J

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

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IN RE: ETHICON, INC. MDL No. 2327
PELVIC REPAIR SYSTEM,
PRODUCTS LIABILITY
LITIGATION

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THIS DOCUMENT RELATES TO ALL CASES

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CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

VIDEOTAPED DEPOSITION OF SEAN M. O'BRYAN

Thursday, June 6th, 2013
9:53 a.m.

Held At:
Campbell Campbell Edwards & Conroy, PC
One Constitution Center
Boston, Massachusetts

REPORTED BY:
Maureen O'Connor Pollard, RPR, CLR, CSR #149108

adverse event and determine if there needed to be further actions?

A. No.

Q. Do you believe that you actually completed and worked on the annual report for TVT Classic during your time at Ethicon?

A. I would have been responsible for the end report.

Q. During your work on the annual report, one of the things that would be in an annual report would be a review of complaints, correct?

A. Right. There would be a group that would feed into -- that information into me, I would make sure that that was included within the annual report.

Q. And you would rely upon that group, whether it's post-marketing surveillance or customer quality, to provide you with accurate information about the complaints that were received?

A. Yes. They would attest that it was complete and accurate.

There is a distinction. I don't think we quantified all complaints. Again, I think they had to reach a certain level of criticality

A. When I was at Ethicon I did work -- I was involved with Ethicon, the TVT Blue product.

Q. What was your work related to TVT Blue?

A. I acted as the regulatory lead for that product.

Q. And what do you mean by "regulatory lead"? Was it similar to your work with TVT Classic?

A. It would have included working on the development, the strategy, the regulatory strategy, being part of the development team. Proposed change comes in, we pull together all disciplines of the team, I would have been the regulatory person on that team.

Q. Similar to your work on TVT-O?

A. Yes, sir.

Q. And did you ultimately work on the 510(k) associated with TVT Blue?

A. I must have. But I don't have a lot of recollection of TVT Blue as a submission.

Q. What about with laser cut mesh?

A. Same answer; I most likely did, but I don't have recollection of a submission associated with laser cut mesh.

Q. You worked on TVT-O, the obturator approach?

A. Yes, I did.

Q. How would you describe your role with TVT-O?

A. I was the regulatory lead on the development team responsible for the regulatory strategy and providing regulatory input towards the development of that product.

Q. And for TVT-S, what was your role?

A. TVT-S, I was not so much involved because I was departing Ethicon, moving up to Massachusetts. I believe I had transitioned prior to becoming the designated regulatory lead for that product.

Q. Do you recall that you started on that product, but then you were getting ready to leave?

A. I had some very early involvement, yes, so -- you know, not formalizing regulatory strategy, but some work on initial considerations in draft.

Q. Outside of the TVT family of products and Monitorr that we've discussed, what other products did you work on while at Ethicon?

Q. And it's entitled actually "Modified Gynecare TVT Obturator System Special 510(k)," correct?

A. Yes.

Q. And if you turn to -- on the bottom you can see the Bates numbers -- if you turn to the Bates number that is 934, and there's a date at the top that says November 10, 2003. Do you see that?

A. Yes.

Q. And this is, on November 10, 2003 is when you, in fact, submitted the 510(k) for TVT-O to the FDA, correct?

A. Yes.

Q. And again, it's described up in the corner as "Special 510(k): Device Modification: Gynecare TVT Obturator System," correct?

A. Yes.

Q. And it states "Modified Device" off to the left there. Do you see that, "Modified Device"?

A. Yes.

Q. And "Gynecare submits this Notification of Intent to market a modification to the TVT System as described within this

that we were just looking at, right?

A. Right.

Q. I'd like to talk about during the design and development phase -- let me back up.

That was the IFU as presented to the FDA in November of 2003, correct?

A. Correct.

Q. And that was the one upon which the FDA would have based its decision about whether or not to approve this Special 510(k)?

A. Correct.

Q. If you back up in time earlier in the year of 2003, during the design and development phase before sending that IFU to the FDA, you were part of the team that created that IFU, is that right?

A. Yes, I was a member of the team.

MR. ZONIES: I'm going to hand you what's been marked as Exhibit T-473.

(Whereupon, Exhibit Number T-473, E-mail chain, Bates ETH.MESH.06879415 through 9417, was marked for identification.)

BY MR. ZONIES:

Q. And it's a series of e-mails, and like